REMARKS

Claims 7, 10-12, 28-35, 37-40, 43, 46. and 54-59 are pending in the application with entry of this Amendment. Claims 7, 28 and 43 are currently amended. The specification is amended consistent with embodiments illustrated in various figures. The claim and specification amendments do not present new matter, particularly considering that support for a claim amendment can be found in the claims as filed, the written description and/or the figures. *See, e.g.*, Figs. 29-32. Claims 12 and 29 were withdrawn from consideration. It is respectfully requested that these claims be reinstated upon allowance of respective independent claims from which they depend. Reconsideration and allowance of the application, as amended, are respectfully requested.

I. Withdrawn Rejections

Applicant acknowledges that the following rejections involving U.S. Patent No. 4,469,105 to Staver ("Staver") were withdrawn following the Amendment submitted on February 17, 2009:

a. Rejection of claims as allegedly being unpatentable over U.S. Patent No. 6,185,442 to Samson ("Samson") in view of Staver and U.S. Patent No. 4,736,749 to Lundback ("Lundback").

b. Rejection of claims as allegedly being unpatentable over Samson in view of Staver and Lundback and further in view of U.S. Patent No. 7,149,575 to Ostroff ("Ostroff").

c. Rejection of claims as allegedly being unpatentable over Samson in view of Staver and Lundback and further in view of U.S. Patent No. 7,020,531 to Colliou ("Colliou").

New grounds of rejection involve U.S. Patent No. 5,295,481 to Geeham ("Geeham"). Staver is no longer relied upon to reject any pending claim.

II. Rejection Under 35 U.S.C. §112¶1 Is Moot

Claims 7 and 28 stand rejected under 35 U.S.C. §112¶1 as allegedly failing to satisfy the written description requirement. For clarification and to expedite prosecution, the specification has been amended to specify that the tissue stimulation element is not located within an inner

space defined by the suction device due to being located on peripheral sealing surface instead. Further, the specification is amended to recite that the tissue stimulation element is a discrete element that does not extend around the peripheral sealing surface, consistent with the drawings which, as acknowledged in the Office Action, suggest such subject matter. Office Action, p. 2. MPEP §608.01 ("While an applicant is not limited to the nomenclature used in the application as filed, he or she should make appropriate amendment of the specification whenever this nomenclature is departed from by amendment of the claims so as to have clear support or antecedent basis in the specification for the new terms appearing in the claims.").

Accordingly, Applicants respectfully submit that the rejection of claims 7 and 28 under 35 U.S.C. §112¶1 be withdrawn.

III. Erroneous Citation of Lundback in Office Action

Applicant noted in the amendment submitted on February 17, 2009 that the Office Action did not cite any section of the cited U.S. Patent No. 4,646,747 to Lundback that actually referred to quoted section discussed on page 5 of the current Office Action (involving EGG, EMG, laser-Doppler, ph, etc.) and that the Lundback patent that was actually cited did not even refer to terms such as "EMG" or "Doppler" or "therapeutic" devices or other words in this quoted section. Given these ambiguities, Applicants requested the Examiner to clarify the basis of the rejection and to identify the section of Lundback relied upon as disclosing the quoted section. However, the Office Action provided no clarification in response to this request.

Upon reviewing other references naming Lundback as an inventor, Applicants believe that they have determined the source of this ambiguity. It appears that while the Office Action, p. 3, cites U.S. Patent No. 4,646,747 to Lundback, the Examiner may have intended to refer to a different patent to Lundback, *i.e.*, U.S. Patent No. 4,736,749, which appears to include the quoted section recited in the last nine lines of page 5 of the Office Action.

Clarification regarding this inconsistency is respectfully requested. Further, Applicants request the examiner to clarify whether the rejection is based on the '747 patent to Lundback, the '749 patent to Lundback, or both of these patents.

IV. Inconsistent Citation of Components of Samson

It is stated in the Office action that "More specifically, the flexible suction tube 15 meets the flexible tube, whereas previous to this amendment 17 was the flexible tube." Office Action (p. 11, second full paragraph) (emphasis added). It is further stated that the reason for this new interpretation and ground of rejection is due to Applicant's amendment to claims 7 and 28 regarding the suction applied through the flexible tube. Office Action (p. 11, second full paragraph). Thus, it is Applicants' understanding that component "17" is not currently relied upon since the current Office Action now relies on "15" instead as a result of the prior amendment.

However, upon reviewing the Office Action, page 3 alleges that "15" is a flexible tube, but then in the same sentence, refers to distal end of "tube (portion 17)." Accordingly, it is not clear which component, 15 or 17, is relied upon as allegedly being a "flexible tube" as recited in Applicant's claims since it is stated in the Office Action that "17" was not alleged to be a "flexible tube" as recited in the claims.

Clarification of these Office Action remarks is respectfully requested since the basis of the rejection is not clear in view of inconsistent citation of components 15 and 17.

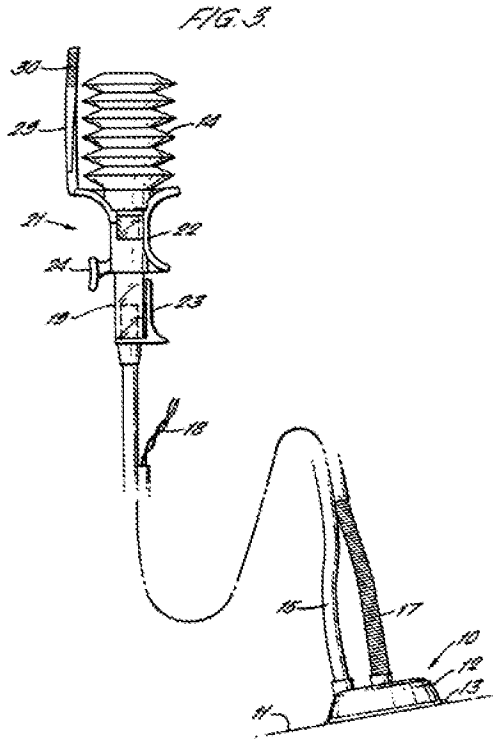
V. Claims 7, 10, 11, 28, 30, 40, 43, 46, 47 and 54-59 Are Patentable Over Samson in view of Geeham and Lundback

Independent claims 7, 28 and 43 and respective dependent claims 10, 11, 30, 40, 46, 47 and 54-59 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Samson in view of Geeham and Lundback (noting again that page 3 of the Office Action refers to U.S. Patent No. 6,646,747 to Lundback, but it appears that the Office Action relies on U.S. Patent No. 4,736,749 to Lundback instead). Applicant respectfully traverses the rejection in view of the deficiencies of the cited references, individually and collectively.

First, the cited components and sections of Samson fail to disclose "a flexible tube defining a central axis and having a proximal end and a distal end" and "a suction device formed from a flexible material, the suction device being connected to and coaxial with the distal end of the tube…" as recited in claims 7 and 43; "a flexible tube, operably connected to suction source, the tube defining a central axis and having a proximal end and a distal end" and "a suction

device formed from a flexible material, the suction device being connected to and coaxial with the distal end of the tube …" as recited in claim 28.

It is alleged that the tube 15 described by Samson is a "flexible tube" as recited in claims 7, 28 and 43. As discussed above, it was previously alleged that "17" was the flexible tube, but in the current Office Action, it is apparently alleged that "15" is the flexible tube recited in these claims due to Applicant's prior amendment. Office Action (p. 11, second full paragraph). It is then apparently alleged, despite the remarks on p. 11 of the Office Action that "17" was alleged to be the "flexible tube" in the prior Office action, that "17" is a tube, and that "10" of Samson is a "suction device" as recited in these claims. Fig. 3 of the cited Samson reference that shows cited components is reproduced below for reference.



As shown in Samson, Fig. 3 above, the tube 15 clearly does not define a central axis and a suction device that is connected to and coaxial with the distal end of tube. To the contrary, the tube 15 is joined to the wall 12 of the suction cup 10 near the top left edge of the wall such that the suction cup 10 is not coaxial with the tube 15. Any allegation to the contrary clearly disregards the well understood meaning of coaxial and Samson, Fig. 3.

Further, Samson actually explains that "17" is an "electrode formed of coiled wire 17." Samson (col. 3, lines 48-49). Samson actually refers to "17" as a "coiled wire." Samson (col. 3, line 49). The Office Action has not established, and Samson does not explain, that this "coiled wire" 17 is in fact a tube. For example, based on the structure shown in Figs. 1 and 3 of Samson, wires 18 may terminate at the proximal end of a solid coiled wire electrode 17.

Nevertheless, Samson further explains that the coiled wire electrode is "provided outside the suction cup [10] for making contact with the vaginal wall." Samson (col. 3, lines 49-50). Accordingly, the coiled wire electrode 17, even assuming that it is somehow properly considered to be a "flexible tube" as recited in the claims, despite the description provided by Samson and the lack of extrinsic evidence in the Office Action establishing that the electrode 17 is necessarily a flexible tube, the coiled wire electrode 17, as its name implies, is not used to apply vacuum or suction to secure the suction cup 10 to the head 11 of a fetus. Instead, Samson explains that non-coaxial tube 15 discussed above is used for this purpose. Samson explains that "the vacuum source is a bellows 14 interconnected to the suction cup [10] by a tube 15." Samson (col. 3, lines 44-46). Accordingly, Samson fails to disclose limitations of claims 1, 28 and 43 directed to a flexible tube defining a central axis and a suction device that is connected to and coaxial with a distal end of the tube, and the Office Action remarks are clearly deficient in this regard and cannot support the rejection.

Second, Samson describes a device directed to applying a suction cup 10 to a head 11 of a fetus, in contrast to a suction device that is coaxial with the distal end of the tube and having a flexible distal portion that includes a flexible peripheral sealing surface having a shape and a size for being removably securable to myocardial tissue by suction applied through the flexible tube.

Third, as conceded in page 4 of the Office Action, Samson also fails to disclose a suction device that includes "the tissue stimulation element being supported on the peripheral sealing surface of the distal portion of the suction device such that the tissue stimulation element is not located within an inner space defined by the suction device, wherein the tissue stimulation element is a discrete tissue stimulation element that does not extend around the peripheral sealing surface" as recited in claims 7 and 28 and metallic or metal based tissue stimulation means, "carried by the peripheral sealing surface of the distal portion of the suction device distal surface such that the tissue stimulation means is not located within an inner space defined by the

suction device, wherein the tissue stimulation means does not extend around the peripheral sealing surface" as recited in claim 43.

Fourth, also as conceded in page 4 of the Office Action, Samson fails to disclose "a metallic or metal-based tissue stimulation element … supported on the peripheral sealing surface of the distal portion of the suction device such that the tissue stimulation element is not located within an inner space defined by the suction device" as recited in claims 1 and 28 and "metallic or metal based tissue stimulation means, carried by the peripheral sealing surface of the distal portion of the suction device distal surface such that the tissue stimulation means is not located within an inner space defined by the suction device…" as recited in claim 43. In contrast, Samson describes "an electrode 16 for making electrical contact with the fetal skin" and that this electrode is mounted "within the suction cup [10]." Samson (col. 3, lines 47-48 (emphasis added). Samson further explains that this structure allows the electrode 16 to be drawn down into contact with the scalp of the fetus as the cup becomes secured on the fetal head. Samson (col. 3, lines 59-61). Thus, as described by Samson, the electrode 16 is not carried on a peripheral sealing surface of the distal portion, and Samson is further deficient in that the electrode 16 is positioned within the suction cup 10. In this regard, Samson describes a structural configuration that is the opposite of the configuration recited in claims 7, 28 and 43.

Geeham is cited for the limited purpose of alleged disclosing a suction device having electrodes 32. Office Action (p. 4). Geeham, however, does not cure all of the substantial deficiencies of Samson and has its own deficiencies.

Geeham describes a CPR assist device that includes a column member 16, handles 18a and 18b, and a suction cup member 20. Defibrillation electrodes 32 are located at the peripheral rim 30 of the suction cup member 20. During use, an aid giver grabs the handles 18a, 18b and administers cycles of compression and expansion by pressing down on the chest and pulling up away from the chest. The suction cup member 10 provides a transfer or force safely and noninjuriously to the patient, and the act of pulling the CPR assist device away from the patient's chest results in a suction action that draws the chest upwardly with the movement of the suction cup member. Geeham (col. 4, lines 19-37).

Thus, Geeham fails to disclose, and is not related to, the combination of a "flexible tube defining a central axis and having a proximal end and a distal end" and "a suction device formed from a flexible material, the suction device being connected to and coaxial with the distal end of

the tube and having a flexible distal portion that includes a flexible peripheral sealing surface having a shape and a size for being removably securable to myocardial tissue by suction applied through the flexible tube" as recited in claims 7 and 28 and "a flexible tube defining a central axis and having a proximal end and a distal end" and "a suction device formed from a flexible material, the suction device being connected to and coaxial with the distal end of the tube and having a flexible distal portion that includes a flexible peripheral sealing surface having a shape and a size for being removably securable to myocardial tissue by suction applied through the flexible tube" as recited in claim 43.

In fact, Geeham does not even mention applying suction through any tube and instead relies only on the deformation of the suction cup 20 to apply suction to the chest. Further, the device described by Geeham is not designed for applying suction through a tube to the suction cup member 20.

Further, given the well known manner in which the CPR assist device is intended and designed to be utilized, the device described by Geeham is not designed for securing the suction cup member 20 to myocardial tissue. Instead, as is well known to a person skilled in the art, the assist device described by Geeham is configured for use on an outer surface of a patient's chest, not on the surface of the patient's heart. Geeham (Fig. 1) (illustrating application of device to outer chest surface). In this regard, Geeham describes a system that is used for a very different purposes and in very different ways. The Office Action has not established, understandably so, that such a device would be utilized by opening a chest cavity and then applying the suction cup member 20 to myocardial tissue. Moreover, it is reasonable to assume that actually applying the suction cup device 20 to myocardial tissue and utilizing the CPR assist device as described by Geeham (by an aid giver pushing down and expanding upon the heart) may result in severe injury and/or death, not only from the compressions, but also from opening the patient's chest.

Geeham also fails to disclose a metallic or metal-based tissue stimulation element configured to emit stimulation energy and that is too small to form a transmural lesion in myocardial tissue "and that is used to stimulate tissue and sense electrical activity in the tissue" as recited in claims 7 and 28 and metallic or metal based tissue stimulation means "for stimulating tissue and sensing electrical activity in the tissue" as recited in claim 43. Rather, as conceded in pages 4-5 of the Office Action, Geeham is instead directed to a defibrillation system that utilizes high voltage circuits to provide "periodic pretimed shocks of electricity" to the

electrodes in order to resuscitate a patient. Geeham (col. 3, lines 28, 41, 53-55). Clearly, and as is well understood by persons skilled in the art, defibrillation systems are not related to and do not involve stimulation elements that emit stimulation energy for sensing activity in tissue, e.g., for pacing, recording and determining whether a transmural lesion has been formed.

Thus, while Geeham may disclose a heart-related device, the structure and functionality of a CPR assist and defibrillation device described by Geeham are very different and not related to Applicant's claims, particularly considering that the CPR assist device does not include a suction device connected to and coaxial with the distal end of the tube and having a flexible distal portion that includes a flexible peripheral sealing surface having a shape and a size for being removably securable to myocardial tissue by suction applied through the flexible tube. Thus, not only is Geeham deficient relative to these claim limitations, but Geeham also teaches away from devices having a shape and size or being removably securable to myocardial tissue by suction applied through the flexible tube.

Lundback is cited for the very limited purpose of allegedly disclosing a surgical apparatus comprising a flexible tube (8) and a tissue electrode, a cup-shaped suction device (1-3 collectively) and a tissue electrode 30 (tissue contacting side of 30) on the suction device distal surface. Office Action (p. 5). Lundback, however, does not cure the substantial deficiencies of Samson and Geeham and has its own deficiencies. Accordingly, the three cited references, even if somehow properly combined, fail to disclose each limitation of each of independent claims 7, 28 and 43 and, therefore, the rejection cannot stand.

Based on what can be determined from the Office Action remarks, it appears that the Examiner relies on U.S. Patent No. 4,736,749 to Lundback rather than U.S. Patent No. 4,646,747, which is actually cited in page 3 of the Office Action.

Lundback fails to disclose the structural combination of a flexible tube defining a central axis and "a suction device formed from a flexible material, the suction device being connected to and coaxial with the distal end of the tube" as recited in claims 7, 28 and 43. In contrast, the tube 8 identified in the Office Action, and as shown in Fig. 4 of Lundback, has an axis that is orthogonal to an axis defined by other components. Thus, Lundback describes a configuration that is the opposite of the configuration recited in the claims.

Further, Lundback fails to disclose "a suction device formed from a flexible material" as recited in claims 7, 28 and 43. In contrast, Lundback describes a suction device having an

electrode plate 1, a sealing component 2, and a back piece 3, and Lundback explains that the cited back piece 3 is **rigid**, the cited intermediate element 2 comprises a "**comparatively stiff**" or "**relatively rigid**" sealing ring 9, and that the device 1 is "**rigidly connected**" to the backpiece 3. Lundback, '749 Patent (Abstract; col. 2, line 4; col. 3, line 46) (emphasis added). Moreover, Lundback explains that various components are **press-stud connected** together such that the therapeutic arrangement 1 is "**rigidly connected**" to the rigid backpiece 3. Lundback, '749 patent (col. 3, lines 29-36) (emphasis added). Accordingly, Office Action allegations regarding Lundback, '749 patent, disclosing a suction device formed from a flexible material clearly ignore the definitive descriptions of cited components as being rigid or stiff and rigidly connected.

Lundback also fails to disclose "a metallic or metal-based tissue stimulation element configured to emit stimulation energy and that is too small to form a transmural lesion in myocardial tissue, the tissue stimulation element being supported on the peripheral sealing surface of the distal portion of the suction device" as recited in claims 7 and 28 and "metallic or metal based tissue stimulation means, carried by the peripheral sealing surface of the distal portion of the suction device distal surface" as recited in claim 43. Lundback describes an intermediate element 2 having a sealing ring 9, but as shown in Fig. 1 of Lundback, '749 patent, the cited operative part 30 is disposed in a middle portion of the device rather than being carried by a peripheral sealing surface of a suction device.

Lundback also fails to disclose a metallic or metal-based tissue stimulation element configured to emit stimulation energy and configured "such that the tissue stimulation element is not located within an inner space defined by the suction device" as recited in claims 7 and 28 and "such that the tissue stimulation means is not located within an inner space defined by the suction device" as recited in claim 43. Rather, as shown in Fig. 1 of Lundback, '749 patent, the operative part 30 is within the inner space defined by the outer edge of the intermediate element 2. Thus, Lundback describes a configuration that is the opposite of the configuration recited in the claims.

Given these collective deficiencies, no proper combination of the three cited references discloses each element of each of independent claims 7, 28 and 43. Accordingly, the rejection cannot stand on this basis alone.

Additionally, the allegation that it would be obvious to modify Samson fails to consider that the claims are directed to a device that is attachable to myocardial tissue by suction and

emitting stimulation energy to cardiac tissue, whereas Samson is directed to a non-invasive sensing device that is applied to the head of a fetus, and Geeham is related to an unrelated purpose of assisting with CPR by use of a device applied to a chest of a patient. Thus, the allegations do not simply involve simple substitution of components, particularly considering the specific structure involving a first, central electrode 16 within the area defined by the suction cup 10 and a second electrode formed of coiled wire 17 outside of the suction cup 10 for making contact with the vaginal wall and that Geeham is not related to application of suction devices to myocardial tissue.

Further, various references teach away from and disclose a configuration that is the opposite of a configuration recited in the claims.

Samson teaches away from "a metallic or metal-based tissue stimulation element … supported on the peripheral sealing surface of the distal portion of the suction device such that the tissue stimulation element is not located within an inner space defined by the suction device" as recited in claims 1 and 28 and "metallic or metal based tissue stimulation means, carried by the peripheral sealing surface of the distal portion of the suction device distal surface such that the tissue stimulation means is not located within an inner space defined by the suction device…" as recited in claim 43 since Samson describes a device in which an electrode 16 is mounted "within the suction cup [10]." Samson (col. 3, lines 47-48 (emphasis added). Samson further explains that this structure allows the electrode 16 to be drawn down into contact with the scalp of the fetus as the cup becomes secured on the fetal head. Samson (col. 3, lines 59-61).

Samson also teaches away from a flexible tube defining a central axis and having a proximal end and a distal end and a suction device formed from a flexible material, the suction device being connected to and "coaxial with" the distal end of the tube as recited in Applicant's claims. Rather, as discussed above, Samson is directed to a central electrode 16 within the space defined by a suction cup 10 that is drawn into contact with a fetus scalp by suction.

Geeham teaches away from a suction device that is "removably securable to myocardial tissue by suction applied through the flexible tube" since Geeham relates to CPR devices, and it is well understood that such CPR devices do not involve opening a patient's chest to apply a suction cup to a myocardial surface of the patient since doing so may result in server injury and/or death of the patient.

Further, to the extent that the suction level achieved utilizing a suction cup 20 is sufficient or advisable for performing CPR, Geeham also teaches away from an external source of suction since such additional suction may result in excessive pulling on the patient's chest.

Lundback also teaches away from a flexible tube defining a central axis and having a proximal end and a distal end and a suction device formed from a flexible material since, as discussed above, Lundback actually refers to rigid and stiff materials and rigid connections achieved using press-stud connections.

Lundback also teaches away from such a flexible tube being coaxial a suction device since Lundback describes a configuration that is the opposite of the configuration recited in Applicant's claims.

Given these substantial deficiencies, it is respectfully submitted that independent claims 7, 28 and 43 are patentable over the three cited references. Dependent claims 10, 11, 30, 40, 46, 47 and 54-59 incorporate the elements and limitations of respective independent claims 7, 28 and 43 and, therefore, are also believed patentable over these references.

Accordingly, it is respectfully requested that the rejection of these claims under §103(a) be withdrawn.

VI. Claims 31-33 and 37-39 Are Patentable Over Samson, Geeham, Lundback and Ostroff

Claims 31-33 and 37-39 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Samson in view of Geeham and Lundback and further in view of U.S. Patent No. 7,149,575 to Ostroff *et al.* (hereafter "Ostroff"). These claims incorporate the elements of respective independent claims 7 and 28 and, therefore, are also believed patentable over the cited references since Ostroff does not cure the substantial and determinative deficiencies discussed above.

Further, Applicant notes that while the Examiner has provided remarks regarding the dimensions of certain electrodes, the dimensions discussed are on the order of millimeters and fractions thereof, whereas it would be expected that the CPR / defibrillation device described by Geeham would involve electrodes of a larger size since these electrodes are use to deliver sufficiently high levels of energy in order to re-start a patient's heart.

A similar analysis applies to Samson, which describes a bellows 14 that is actuated by hand to attach a suction cup 10 to a head 11 of a fetus. Further, Applicant notes that Fig. 1 shows the central, internal electrode 16 being larger or wider than the coiled wire 17. Thus, it is reasonable to assume, in the absence of a description to the contrary, that the electrode 16 is not on the order or millimeters but instead is a larger electrode for providing for manual manipulation of the bellows 14.

Accordingly, it is respectfully requested that the rejection of these claims under §103(a) be withdrawn.

VII. Claims 34 and 35 Are Patentable Over Samson, Geeham Lundback and Colliou

Claims 34 and 35 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Samson in view of Geeham and Lundback and further in view of Colliou. Colliou is cited for the very limited purpose of allegedly disclosing certain stimulation pulses, but Colliou does not cure the substantial and determinative deficiencies discussed above.

Accordingly, it is respectfully requested that the rejection of these claims under §103(a) be withdrawn.

CONCLUSION

Applicant respectfully requests entry of this Amendment and allowance of the application in view of the forgoing remarks. If there are any remaining issues that can be resolved by telephone, Applicant invite the Examiner to kindly contact the undersigned at the number indicated below.

Respectfully submitted,

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Dated: August 31, 2009

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